

P A T E N T

**UNITED STATES PATENT AND TRADEMARK OFFICE**

In re: Sean McFerran Confirmation No.: 7830  
Serial No.: 10/667,056 Examiner: Phillip A. Gray  
Filing Date: September 22, 2003 Group Art Unit: 3767  
Docket No.: 1001.1708101 Customer No.: 28075  
For: MICROCATHETER WITH SLEEVED GUIDEWIRE PORT

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

**CERTIFICATE FOR ELECTRONIC TRANSMISSION:**

The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 12th day of February 2007.

By Kathleen L. Boekley  
Kathleen L. Boekley

Dear Sir:

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this Request.

This Request is being filed with a Notice of Appeal.

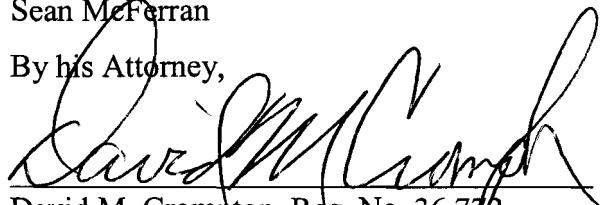
The review is requested for the reasons stated on the attached five sheets of arguments.

This Request is signed by an attorney or agent of record.

Respectfully submitted,

Sean McFerran

By his Attorney,

  
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Date: 2/12/07

Attachment: Five Sheets of Pre-Appeal Brief Request Attachment

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**PRE-APPEAL BRIEF REQUEST FOR REVIEW ATTACHMENT**

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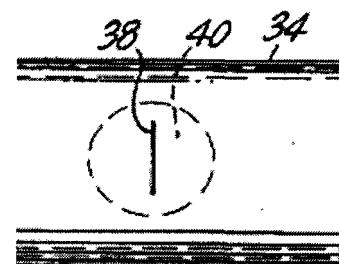
Dear Sir:

Applicants have carefully reviewed the Final Office Action of September 12, 2005 and the Advisory Action of November 28, 2005. Claims 13 and 15-20 are pending in this application wherein claims 13 and 15-17 have been rejected. Applicants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 13 and 15-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Alchas (U.S. Patent No. 5,030,210) in view of Person et al. (U.S. Patent No. 5,807,349). Appellants respectfully submit that no *prima facie* case of obviousness has been made for at least the reasons that the references do not teach or suggest each and every element of the claimed invention and that there is no motivation to modify the references as suggested. The Examiner makes the *prima facie* rejection in three steps, first asserting that Alchas contains certain claimed elements, then modifying Alchas in view of Person, and finally modifying this modified catheter to produce a catheter that corresponds to that claimed. In each step there are serious deficiencies.

For example, claim 13 recites “an elongate guidewire port,” an element the cited prior art references do not disclose. The Examiner asserts that opening 40 of Alchas is an elongate

guidewire port.<sup>1</sup> (This circular opening can be seen in Figures 7 and 8.) When Appellants pointed out that Alchas does not in fact disclose an elongate guidewire port, the Examiner reaffirmed the previous assertion, saying that “since element (40) is fully capable of all structural, functional, spatial, and operational limitations associated with the claim language of ‘Elongate guidewire port’.”<sup>2</sup> However, circular is not elongate. The Examiner is obligated to interpret the claims as broadly as their term reasonably allow, which means that the claim terms must be given their plain meaning unless the plain meaning is inconsistent with the specification.<sup>3</sup> The plain meaning of elongate is “having more length than width.”<sup>4</sup> Opening 40 of Alchas is circular and therefore has the same length and width. (This is shown to the right, which is a portion of Figure 8 of Alchas.) To say that opening 40 is “an elongate guidewire port” is to interpret that phrase in a manner that impermissibly ignores “elongate.” No person of ordinary skill in the art would reasonably understand opening 40 of Alchas to be an elongate opening. When the language of claim 13 is construed in a permissible manner, it is clear that opening 40 of Alchas cannot reasonably be considered an “elongate guidewire port.” Appellants therefore respectfully submit that Alchas does not disclose at least this element of claim 13.



A second deficiency in the rejection is that the suggested motivation for modifying Alchas in view of Person et al. is inapplicable to the modification. The proposed modification is an angled slit. The angle in question is not the overall disposition of the slit in the sheath (the sheath is disposed parallel to a longitudinal axis of the guidewire) but rather how the slit is “cut” into the membrane. The angle of such an angled slit can be seen in Figure 7 of the application.

The Examiner asserts that it would be obvious to modify Alchas in view of Person et al. for reasons given in Person citing in particular column 5, lines 17-30 of Person et al. However, Person et al. are not here talking about *a slit* but about *a pair of slits* disposed on intersecting

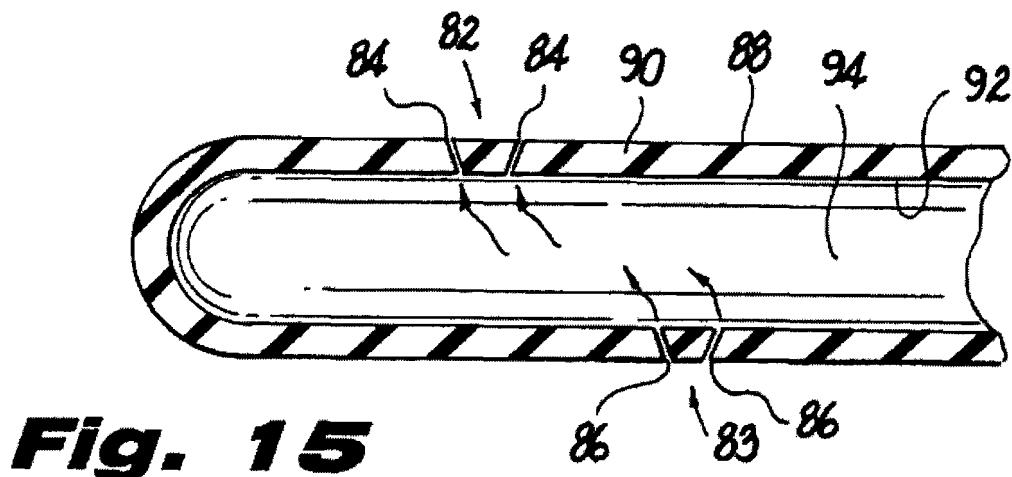
<sup>1</sup> September 12, 2005 Office Action, Page 2

<sup>2</sup> September 12, 2005 Office Action, Page 4

<sup>3</sup> MPEP 2111.01 citing *In re American Academy of Science Tech Center*, 70 USPQ2d 1827 (Fed. Cir. 2004), *In re Zletz*, 13 USPQ2d 1320 (Fed. Cir. 1989), and *Chef America, Inc. v. Lamb-Weston, Inc.*, 69 USPQ2d 1857 (Fed. Cir. 2004).

<sup>4</sup> *The American Heritage Dictionary, Fourth Edition*

planes. The slits “are cut at an angle from the outer surface 88’ through wall 90’ to inner surface 92’ such that one of the slits 84’ is cut in the direction of the other slit 84’ ” and “intersection interiorly within the catheter 80 within lumen 94.”<sup>5</sup> Because the pair of slits are cut in this manner, the valve 82’ which is formed from the slits “opens outwardly in response to increased pressure from the lumen 94 of the catheter.”<sup>6</sup> The next paragraph in the specification describes valve 83’ in which a pair of slits are configured in an opposite configuration.<sup>7</sup> Valves 82’ and 83’ are shown in Figure 15:



**Fig. 15**

The final paragraph describing the embodiment of Figure 15 describes how pressure in the lumen seals valve 83 and how a decrease of pressure in the lumen seals valve 82. Person et al. are describing a pair of one-way valves, each of which is made from a pair angled slits in the catheter wall.

However, Person et al. are silent with regard to a single angled slit - what one would do with it or why one might make it. Thus the motivation that the Examiner cites, which is from this section of the specification describing pairs of slits, is not applicable to a single slit and therefore does not constitute a motivation to angle a single slit. Appellants therefore respectfully submit that there is no motivation to modify Alchas in view of Person et al.

A further deficiency in the *prima facie* rejection is proposed motivation for modifying the modified catheter to align the slit with the longitudinal axis of the shaft. The Examiner asserts

<sup>5</sup> Person et al., col. 5, lines 22-26.

<sup>6</sup> Person et al., column 5, lines 27-29.

<sup>7</sup> Person et al., column 5, lines 31-39.

that it would have been obvious to make the slit parallel to the longitudinal axis, first saying that “it would have been an obvious matter of design choice to position the slit parallel along the longitudinal axis, since applicant has not disclosed that the parallel slit over the angled slit solves any stated problem or is for any particular purpose,” and then saying that “in the alternative one of ordinary skill in the art would have made a modification to make the slit parallel to the longitudinal axis because it would be an obvious modification and it has been held that rearranging parts of an invention involves only routine skill in the art.”<sup>8</sup> However, the fact references can be modified or that a claimed invention is within the inventive capabilities of one of ordinary skill in the art is not sufficient by itself to establish *prima facie* obviousness.<sup>9</sup> Moreover, “the mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claim on appeal is not by itself sufficient to support a finding of obviousness.”<sup>10</sup>

The claimed invention is not an obvious design choice over the cited references for at least the reason that Person et al. teach away from it. Person et al. teach “in each of the embodiments, it is preferred that the valves are positioned at an angle to the longitudinal axis of the catheter in an area of reduced thickness to increase the size of the opening for the ingress and egress of fluids.”<sup>11</sup> Thus, a longitudinally aligned slot is not an obvious design choice over Person et al. Such a modification would reduce the size of the opening for the ingress and egress of fluids. Both the catheters of Person et al. and Alchias are used for fluid passage. Thus the proposed modification, which has been criticized by Person et al., would make the proposed catheter less suitable for its intended use. Because the proposed modification has been criticized by Person et al., one cannot say that it is an obvious matter of design choice or a mere matter of rearranging the parts. Appellants therefore submit that there is no motivation to modify the catheter so that the slit is parallel to the longitudinal axis of the shaft.

Overall, it can be seen that the *prima facie* case of obviousness has serious deficiencies: all claim elements have not been taught or suggested and there is no motivation to combine the references or to make the suggested modifications. Moreover, the cited art pertains to catheter

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<sup>8</sup> September 12, 2005 Office Action, page 3.

<sup>9</sup> See MPEP 2143.01 parts III and IV.

<sup>10</sup> MPEP 2144.04 citing *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351 (Bd. Pat. App. & Inter. 1984).

<sup>11</sup> Person et al., column 2, lines 30-34.

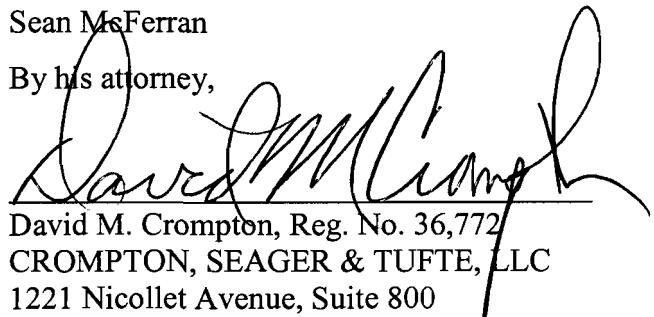
used for the movement of fluids whereas the catheter of claim 13 contains features that are suited for use with a guidewire. The elongate guidewire port, for example, has sufficient width to allow for the passage of a guidewire but may also be narrow enough to provide support to the sheath to reduce the possibility that the movement of the guidewire through the port will damage the sheath and make the slit less fluid tight. Further, the elongate nature of the port permits the easy insertion of the guidewire into the port and permits angling the guidewire in the desired direction while keeping the area of the port relatively small (a larger port is a greater weakness in the catheter wall).

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Sean McFerran

By his attorney,



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